

**AMENDMENT**

**U.S. Appln. No. 10/023,831**

**REMARKS**

On page 2 of the Office Action, the Examiner contends that the application does not comply with the sequence requirements because Applicants have failed to include a statement that the Sequence Listing filed June 19, 2002, adds no new matter.

Accordingly, Applicants submit herewith a copy of the Statement in Support of Submission (along with a copy of the date-stamped mailroom receipt therefor) submitted with the Sequence Listing on June 19, 2002.

On page 3 of the Office Action, the Examiner rejects Claims 31-35 under 35 U.S.C. § 101 as being directed to a product of nature, i.e., it is the Examiner's position that the claims encompass any naturally occurring hydroxylated polypeptide comprising a triple helix (e.g., collagen), or any biological material comprising said protein. The Examiner suggests that the claims be amended to recite "isolated" or "purified", to overcome this rejection.

For the following reasons, Applicants respectfully traverse the Examiner's rejection.

Applicants respectfully submit that the hydroxylated triple helical proteins in the amended claims are not products of nature, and, for example, do not include collagen within the scope thereof. That is, in amended Claim 31, at least one of m and o is 1, and thus the polypeptide or peptide defined by Claim 31, comprises a polypeptide or peptide domain which is heterologous to collagen proteins and which does not comprise a triple helical forming repeating sequence. Hence, Claim 31 defines a hydroxylated triple helical protein that is non-naturally occurring, indeed, Claim 31 recites that the polypeptide or peptide is "synthetic".

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Accordingly, Applicants request withdrawal of the Examiner's rejection.

On pages 3-7 of the Office Action, the Examiner rejects Claims 31-35 under 35 U.S.C. § 112, first paragraph.

Specifically, the Examiner states that while the specification is enabling for a hydroxylated triple helical protein, wherein the protein is a collagen, such does not provide enablement for the broad scope of the claims.

For the following reasons, Applicants respectfully traverse the Examiner's rejection.

Applicants respectfully submit that the specification provides the skilled artisan with sufficient information to reproduce the present invention without inventive activity. The Examiner will note that Claim 34 has been amended to indicate that the biomaterial is formed from collagens, natural and synthetic collagen fragments, and natural and synthetic collagen-like proteins.

Accordingly, Applicants respectfully submit that the claims are enabled by the present specification, and thus request withdrawal of the Examiner's rejection.

On pages 7-8 of the Office Action, the Examiner rejects Claims 31-35 under 35 U.S.C. § 112, second paragraph.

Specifically, the Examiner contends that the claims are indefinite because only a small fraction of the peptides described by the formula set forth in Claim 31 would form a triple helix.

For the following reasons, Applicants respectfully traverse the Examiner's rejection.

Applicants respectfully submit that the person skilled in the art would be able to reproduce the invention defined in

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Claims 31 to 35 without inventive activity. As noted by the Examiner, Claim 31 specifically states that the polypeptide is a hydroxylated triple helical protein. The skilled artisan, armed with the knowledge in the art and the disclosure of the present specification could readily reproduce the invention defined by the present claims.

The Examiner also contends that the claims are indefinite in reciting "(GlyXY)<sub>n</sub>", in the 24<sup>th</sup> and 29<sup>th</sup> lines of Claim 31, as the subscript "n" is not defined, and it is not clear how this term differs from "(GlyXY)<sub>1</sub>" which appears earlier in the claim.

The Examiner is requested to note that amended Claim 31 specifies a value for subscript "n", thereby rendering moot the Examiner's rejection.

The Examiner also contends that Claim 32 is indefinite in reciting "domain Z comprises no more than 10 to 300 GlyXY repeats".

Claim 32 has also been amended to indicate that domain Z comprises 10 to 300 GlyXY triplets, thereby rendering moot the Examiner's rejection.

Accordingly, Applicants respectfully submit that the claims clearly and definitely recite the invention of interest, and thus request withdrawal of the Examiner's rejection.

On page 8 of the Office Action, the Examiner rejects Claims 31-33 under § 102(b) as being anticipated by Fields et al.

Specifically, the Examiner contends that Fields et al teaches a variety of artificial peptides comprising Gly-Pro-Hyp, where Hyp is a hydroxypropylene which forms triple helixes (see Table 1 and Figure 1 thereof), which the Examiner contends falls within the scope of Claim 31. Further, the Examiner states that

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Fields et al teaches repeat domains of 9 (e.g.,  $\alpha 1(\text{IV})531-543$ ) to 13 (e.g.,  $\alpha 1(\text{IV})1263-1277$ ) repeat units as defined in Claim 32, and repeat units which are at least three times greater than the combined length of the E and F domains comprised by the peptides (e.g.,  $\alpha 1(\text{IV})1263-1277$ ,  $\alpha 1(\text{IV})1263-1277772-786$ , etc.) as claimed in Claim 33.

For the following reasons, Applicants respectfully traverse the Examiner's rejection.

As noted above, Claim 31 has been amended such that at least one of m or o is 1, i.e., such that the synthetic peptide or polypeptide of Claim 31 includes a domain that is heterologous to collagen proteins and which does not comprise a triple helical forming repeating sequence. Fields et al does not teach or suggest a peptide or polypeptide according to amended Claim 31.

Accordingly, Applicants respectfully submit that the present invention is not taught or suggested in Fields et al, and thus request withdrawal if the Examiner's rejection.

On page 9 of the Office Action, the Examiner rejects Claims 31-32 and 34 under 35 U.S.C. § 102(b) as being anticipated by Silver et al.

Specifically, the Examiner states that Silver et al discloses a hydroxylated triple helical protein (i.e., bovine type 1 collagen) which is encompassed by Claims 31 and 34, and that the protein can be used in biomaterials and therapeutic products, as recited in Claim 34.

For the following reasons, Applicants respectfully traverse the Examiner's rejection.

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Silver et al is silent with regard to a hydroxylated triple helical peptide that contains as least one heterologous domain as defined in amended Claim 31.

Accordingly, Applicants respectfully submit that the present invention is not taught or suggested in Silver et al, and thus request withdrawal if the Examiner's rejection.

In addition, on page 9 of the Office Action, the Examiner rejects Claims 31-32 under 35 U.S.C. § 102(b) as being anticipated by any one of Swiss-Prot database entries P02745 (1986), P07714 (1988), P35247 (1994), P11226 (1989), P23805 (1991), or P21757 (1991).

Specifically, the Examiner states that each of these database entries teaches a polypeptide comprising a collagen repeat domain which would form a hydroxylated triple helical protein, and thus meet the limitations of the present claims.

For the following reasons, Applicants respectfully traverse the Examiner's rejection.

The data base entries are silent with regard to a hydroxylated triple helical peptide that contains as least one heterologous domain as defined in amended Claim 31.

Accordingly, Applicants respectfully submit that the present invention is not taught or suggested in the data base entries, and thus request withdrawal if the Examiner's rejection.

Finally, on page 10 of the Office Action, the Examiner rejects Claims 31-35 under 35 U.S.C. § 102(e) as being anticipated by St. Pierre et al.

Specifically, the Examiner states that St. Pierre et al teaches a hydroxylated triple helical protein having the characteristics set forth in Formula A described in the section

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entitled "1. Collagen Mimics" beginning at column 3, which meet the limitations of the present claims.

For the following reasons, Applicants respectfully traverse the Examiner's rejection.

St. Pierre et al is silent with regard to a hydroxylated triple helical peptide that contains as least one heterologous domain as defined in amended Claim 31.

Accordingly, Applicants respectfully submit that the present invention is not taught or suggested in St. Pierre et al, and thus request withdrawal if the Examiner's rejection.

In view of the amendments to the claims, and the arguments set forth above, reexamination, reconsideration and allowance are respectfully requested.

The Examiner is invited to contact the undersigned at his Washington telephone number on any questions which might arise.

Respectfully submitted,

  
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